



4 MAY 8 - 1 2001 MAY 15 P2:30

Mr. Jim Roza
Director, Quality Assurance
NOW Foods
395 S. Glen Ellyn Road
Bloomingdale, Illinois 60 108

Dear Mr. Roza:

This is in response to your letter of March 8, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Now Foods is making the following claim, among others, for the product **Glucosol™**:

“ . . . support healthy blood sugar levels. . . . ”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or, prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure or mitigate diseases, namely disorders related to blood glucose levels. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret

Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Chicago District Office, Office of Compliance, HFR-MW140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 978-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-8 10 (Foret)

HFS-811 (r/f, file)

HFD-3 10

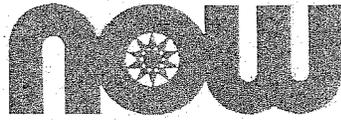
HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

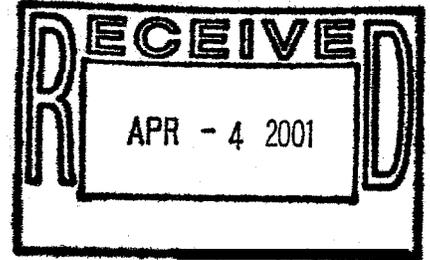
GCF- 1 (Nickerson)

f/t:HFS-811:rjm:4/20/01:docname:75298.adv:disc57



The Future in Natural Foods

75298



March 8, 2001

Office of Special Nutritionals (HF-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Glucosol 24 mg, a dietary supplement.

Statements being made in the labeling of Glucosol 24 mg

- (1) Glucosol™, *Lagerstroemia speciosa* L., is standardized to 1% corosolic acid. It is derived from the Crepe Myrtle, a tree native to southern Asia. Corosolic acid helps to support healthy blood sugar levels.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Now Foods possesses substantiation that the statements are truthful and not misleading.

Jim Roza
Director, Quality Assurance
NOW Foods
395 S. Glen Ellyn Rd.
Bloomington, IL 60 108